

510(k) Summary
per 21 CFR §807.92

SEP 14 2012

Sponsor: Boston Scientific Corporation
One Boston Scientific Place
Natick MA 01760

Contact Person: Holly Ramirez

Phone Number: 763-494-2113

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Prepared: June 05, 2012

Trade Name: Imager™ II 5F Selective Angiographic Catheter

Common Name: Diagnostic Intravascular Catheter

Classification: II

Product Code: DQO/ 21 CFR 870.1200

Predicate Device: Imager™ II Angiographic Catheter (K011664, September 07, 2001) and Renegade STC 18 Microcatheter (K023681 November 26, 2002).

Device Description:

The 5F Selective Imager II Angiographic catheters without sideholes are sterile, single use diagnostic intravascular catheters. These catheters are available in a variety of shapes and lengths depending on the catheter model. The distal segment of the catheter is radiopaque to aid in visualization of the device under fluoroscopy. Clinically, selective catheters are used to create images of specific areas of interest. The Imager II 5F Selective Catheter without side-holes can also be used to deliver embolic materials.

Intended Use

The Imager II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system, including the carotid arteries.

Additionally the 5F Selective Imager II Angiographic Catheters without sideholes can also be used for the controlled and selective delivery of the Boston Scientific Interlock™ -35 Detachable Coils into the peripheral vasculature.

Substantial Equivalence

The Imager II 5F Angiographic Catheters design, materials, manufacturing processes, and intended uses are substantially equivalent to the Imager II Angiographic Catheters (K011664) and the Renegade STC 18 Microcatheter (K023681).

Summary of Non-Clinical Testing

Design verification testing as listed below was performed to verify the performance and usability of the Imager II 5F Selective Angiographic Catheters without sideholes with the Boston Scientific Interlock™ -35 Detachable Coils and to show substantial equivalence to the predicate devices:

- ◆ Embolic Coil Deployment
- ◆ Catheter Compatibility with 0.035" Embolic Coils
- ◆ Embolic Coil Stretch Resistance
- ◆ Introducer Sheath Interface

Summary of Clinical Testing

Clinical Evaluation was not required for these devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Ms. Holly Ramirez
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

SEP 14 2012

Re: K121694

Trade/Device Name: 5F Selective Imager II Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: August 23, 2012
Received: August 24, 2012

Dear Ms. Ramirez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Imager II Angiographic Catheter

Indications For Use:

The Imager II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system including the carotid arteries.

Additionally, the 5F Selective Imager II Angiographic Catheters without sideholes can be used for the controlled and selective delivery of the Boston Scientific Interlock™-35 Detachable Coils into the peripheral vasculature.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR
Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices
File Number K121699

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